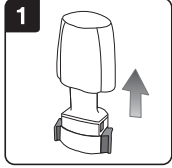


FobunidTM

Formoterol Fumarate Dihydrate BP and Budesonide BP
Inhalation Capsules

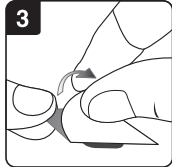
HOW TO USE | কিভাবে ব্যবহার করবেন



Take away the protection cap.
সুরক্ষা ক্যাপটি খুলে ফেলুন।



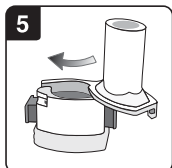
Hold the base of the **Turbohaler** firmly and open the Turbohaler by turning the mouthpiece in the direction of the arrow.
দৃঢ় ভাবে টার্বোহেলার এর নিচের অংশটি ধরুন এবং তীর চিহ্নের দিকে মাউথপিস্টি ঘুরিয়ে টার্বোহেলারটি খুলুন।



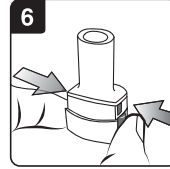
Take a capsule out of the blister strip carefully.
ব্লিস্টার স্ট্রিপ থেকে একটি ক্যাপসুল নিন।



Place the capsule into the Turbohaler capsule chamber.
টার্বোহেলার ক্যাপসুল চেম্বার এর মধ্যে ক্যাপসুলটি রাখুন।

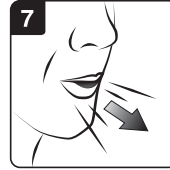


Close the **Turbohaler** by turning the mouthpiece back to the closed position.
মাউথপিস্টি বিপরীত দিকে ঘুরিয়ে টার্বোহেলারটি বন্ধ করুন।



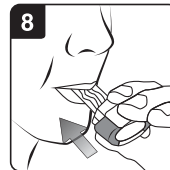
Hold the Turbohaler upright. Hold the two push buttons between thumb and the index finger. Use both fingers at the same time to press the two push buttons once and use quick firm pressure to puncture the capsule evenly. Always release the push buttons before inhalation. Do not press the push buttons more than once to prevent the shattering of the capsule.

টার্বোহেলার খাড়াভাবে ধরুন। পুশ বাটন দুটি বৃদ্ধাঙ্গুলি এবং তর্জনীর মধ্যে ধরুন। পুশ বাটন দুটিতে একবার চাপ দেয়ার জন্য একই সময়ে উভয় আঙুল ব্যবহার করুন এবং সমান ভাবে ক্যাপসুলটি ছিদ্র করার জন্য দ্রুত দৃঢ়ভাবে চাপ প্রয়োগ করুন। সর্বদা শ্বসনের মাধ্যমে গুথুণ গ্রহণের আগে পুশবাটন দুটি ছাড়িয়ে নিতে হবে। ক্যাপসুলের চূর্ণ হয়ে যাওয়া প্রতিরোধ করতে পুশ বাটনগুলোতে একাধিকবার চাপ প্রয়োগ করা থেকে বিরত থাকুন।



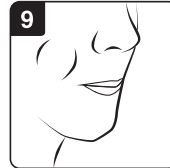
Breathe out (not through the Turbohaler) and hold the Turbohaler upright.

শ্বাস ছেড়ে দিন (টার্বোহেলারের মাধ্যমে নয়) এবং টার্বোহেলার টি খাড়াভাবে ধরে রাখুন।



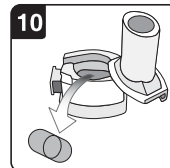
Put your head back slightly. Insert the mouthpiece of the Turbohaler completely into your mouth and breathe in rapidly but steadily, as deeply as possible. The Turbohaler makes a whirring noise if it operates properly. This is because the capsule spins around the chamber as the powder disperse.

আপনার মাথা পিছনে সামান্য হেলিয়ে রাখুন। টার্বোহেলারের মাউথপিস্টি সম্পূর্ণরূপে আপনার মুখের ভেতরে ঢোকান এবং যতটা গভীরভাবে সম্ভব ততটা দ্রুত কিন্তু স্থিরভাবে শ্বাস গ্রহণ করুন। টার্বোহেলারটি সঠিকভাবে ব্যবহৃত হলে একটি শো শো শব্দ তৈরি করবে। ক্যাপসুল থেকে পাউডার বের হওয়ার সময় ক্যাপসুলটির চেম্বারের চার পাশে ক্রমাগত ঘূর্ণনের ফলে এই শব্দ হয়।



Remove the Turbohaler from your mouth and hold your breath for about 5-10 seconds.

আপনার মুখ থেকে টার্বোহেলারটি বের করুন এবং ৫-১০ সেকেন্ডের জন্য আপনার শ্বাস ধরে রাখুন।



After completion of the inhalation remove the empty capsule and rinse your mouth with water.

শ্বসন শেষ হওয়ার পর খালি ক্যাপসুলটি ফেলে দিন এবং পানি দিয়ে আপনার মুখ ধুয়ে ফেলুন।

Cleaning Procedure:

Turbohaler should be cleaned after use. Clean the mouthpiece of Turbohaler with water and then dry it properly to prevent from any water retention. The capsule chamber should be cleaned with a little brush. The perforation needles should be cleaned by pressing the push buttons for few times. Replace the protection cap after cleaning the Turbohaler.

পরিষ্কার প্রণালী:

ব্যবহারের পর টার্বোহেলার পরিষ্কার করে রাখা উচিত। টার্বোহেলার এর মাউথপিস্টি পানি দিয়ে ধুয়ে তারপর ভালোভাবে শুকিয়ে ফেলতে হবে যাতে পানি জমে না থাকে। ক্যাপসুল চেম্বারটি ছোট ব্রাশ দিয়ে ভালো ভাবে পরিষ্কার করতে হবে। পুশ বাটন দুটিতে বারবার চাপ প্রয়োগ করে ছিদ্র করার জন্য ব্যবহৃত সুইগুলো পরিষ্কার করতে হবে। টার্বোহেলার পরিষ্কার করার পরে সুরক্ষা ক্যাপটি প্রতিস্থাপন করুন।

FobunidTM

Formoterol Fumarate Dihydrate BP and Budesonide BP
Inhalation Capsules

DESCRIPTION

FobunidTM Inhalation capsule is used for dry powder inhaler. It is intended for oral inhalation only. It is a combination of Formoterol Fumarate Dihydrate BP and Budesonide BP. Budesonide is a glucocorticosteroid which when inhaled has a dose-dependent anti-inflammatory action in the airways, resulting in reduced symptoms and fewer asthma exacerbations. Inhaled Budesonide has less severe adverse effects than systemic corticosteroids. The exact mechanism responsible for the anti-inflammatory effect of glucocorticosteroids is unknown. Formoterol is a selective β_2 adrenoceptor agonist that when inhaled results in rapid and long-acting relaxation of bronchial smooth muscle in patients with reversible airways obstruction. The bronchodilating effect is dose-dependent, with an onset of effect within 1-3 minutes. The duration of effect is at least 12 hours after a single dose.

PHARMACOLOGY

FobunidTM contains Formoterol and Budesonide, which have different modes of action and show additive effects in terms of reduction of asthma exacerbations. The specific properties of Budesonide and Formoterol allow the combination to be used either as maintenance and reliever therapy, or as maintenance treatment of asthma. Budesonide is a glucocorticosteroid which when inhaled has a dose-dependent anti-inflammatory action in the airways, resulting in reduced symptoms and fewer asthma exacerbations. Formoterol is a selective β_2 adrenoceptor agonist that when inhaled results in rapid and long-acting relaxation of bronchial smooth muscle in patients with reversible airways obstruction.

INDICATIONS

Asthma

Formoterol and Budesonide is indicated in adults and adolescents (12 years and older) for the regular treatment of asthma.

Chronic Obstructive Pulmonary Disease (COPD)

Formoterol and Budesonide is indicated in adults, aged 18 years and older, for the symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV1) <70% predicted normal (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy.

DOSAGE AND ADMINISTRATION FOR ASTHMA:

Maintenance therapy-

Patients should be advised to have their separate rapid-acting bronchodilator available for rescue use at all times.

- **Adults (18 years and older):** 1-2 inhalations twice daily. Some patients may require up to a maximum of 4 inhalations twice daily.
- **Adolescents (12 – 17 years):** 1-2 inhalations twice daily.
- **Children (6 years and older):** A lower strength (100 micrograms/6 micrograms/inhalation) is available for children 6-11 years.
- **Children under 6 years:** As only limited data are available, this combination is not recommended for children younger than 6 years.

In usual practice when control of symptoms is achieved with the twice daily regimen, titration to the lowest effective dose could include this combination given once daily, when in the opinion of the prescriber, a long-acting bronchodilator in combination with an inhaled corticosteroid would be required to maintain control.

Maintenance and reliever therapy-

Adults and adolescents (12 years and older): The recommended maintenance dose is 2 inhalations per day, given either as one inhalation in the morning and evening or as 2 inhalations in either the morning or evening. Patients should take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion.

Children younger than 12 years: This combination is not recommended for children for maintenance and reliever therapy.

For COPD-

Adults: 2 inhalations twice daily.

CONTRAINDICATIONS

Contraindicated in patients with known severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to Formoterol Fumarate Dihydrate and/or Budesonide.

SIDE EFFECTS

No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds. The most common drug related adverse reactions are pharmacologically predictable side effects of β_2 adrenoceptor agonist therapy, such as tremor and palpitations. These tend to be mild and usually disappear within a few days of treatment.

PRECAUTION AND WARNING

It is recommended that the dose is tapered when the treatment is discontinued and should not be stopped abruptly. Complete withdrawal of inhaled corticosteroids should not be considered unless it is temporarily required to confirm diagnosis of asthma. Patients should be advised to have their rescue inhaler available at all times, either this combination (for asthma patients using this combination as maintenance and reliever therapy) or a separate rapid-acting bronchodilator (for all patients using this combination as maintenance therapy only).

USE IN PREGNANCY AND LACTATION

For this combination or the concomitant treatment with Formoterol and Budesonide, no clinical data on exposed pregnancies are available. Data from an embryo-foetal development study in the rat, showed no evidence of any additional effect from the combination. There are no adequate data from use of Formoterol in pregnant women. In animal studies Formoterol has caused adverse effects in reproduction studies at very high systemic exposure levels. Budesonide is excreted in breast milk. However, at therapeutic doses no effects on the suckling child are anticipated. It is not known whether Formoterol passes into human breast milk. In rats, small amounts of Formoterol have been detected in maternal milk. Administration of this combination to women who are breast-feeding should only be considered if the expected benefit to the mother is greater than any possible risk to the child.

OVERDOSE

An overdose of Formoterol would likely lead to effects that are typical for β_2 adrenoceptor agonists: tremor, headache, palpitations. Symptoms reported from isolated cases are tachycardia, hyperglycaemia, hypokalaemia, prolonged QTc-interval, arrhythmia, nausea and vomiting. Supportive and symptomatic treatment may be indicated. A dose of 90 micrograms administered during three hours in patients with acute bronchial obstruction raised no safety concerns. Acute overdosage with Budesonide, even in excessive doses, is not expected to be a clinical problem. When used chronically in excessive doses, systemic glucocorticosteroid effects, such as hypercorticism and adrenal suppression, may appear.

PHARMACEUTICAL PRECAUTION

FobunidTM Inhalation capsules must not be swallowed. Only to be used with Turbohaler. Keep away from light and wet place.

Store at or below 25 °C temperature. Keep out of reach of children. Remove Inhalation capsule from the blister pack only immediately before use in the Turbohaler as Inhalation capsule exposed to moisture may not be pierced easily.

DRUG INTERACTION

Potent inhibitors of CYP3A4 (e.g. Ketoconazole, Itraconazole, Voriconazole, Posaconazole, Clarithromycin, Telithromycin, Nefazodone and HIV protease inhibitors) are likely to markedly increase plasma levels of Budesonide and concomitant use should be avoided. If this is not possible the time interval between administration of the inhibitor and Budesonide should be as long as possible. In patients using potent CYP3A4 Inhibitors, Formoterol Fumarate and Budesonide maintenance and reliever therapy is not recommended.

METHOD OF ADMINISTRATION

Please see opposite side of this leaflet.

PACKAGING

FobunidTM 100 Inhalation Capsules:

Box containing 3 strips of 10 capsules each. Each capsule contains Formoterol Fumarate Dihydrate BP 6 mcg and Budesonide BP 100 mcg.

FobunidTM 200 Inhalation Capsules:

Box containing 3 strips of 10 capsules each. Each capsule contains Formoterol Fumarate Dihydrate BP 6 mcg and Budesonide BP 200 mcg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

TM TRADEMARK

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